Re-evaluation Decision RVD2010-14

Hexahydro-1,3,5-tris (2-hydroxyethyl)-s-triazine (hexahydrotriazine)

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Re-evaluation Decision

After a re-evaluation of the antimicrobial hexahydro-1,3,5-*tris*(2-hydroxyethyl)-*s*-triazine (hexahydrotriazine), Health Canada's Pest Management Regulatory Agency (PMRA), under the authority of the *Pest Control Products Act* and Regulations, is granting continued registration of products containing hexahydrotriazine for sale and use in Canada.

An evaluation of available scientific information found that products containing hexahydrotriazine do not present unacceptable risks to human health or the environment when used according to label directions for most of the uses. As a condition of the continued registration of hexahydrotriazine uses, new risk-reduction measures must be included on the labels of all products. Additional data are required as a result of this re-evaluation.

The regulatory approach for the re-evaluation of hexahydrotriazine was first presented in Proposed Re-evaluation Decision document PRVD2010-06, *Hexahydrotriazine*, a consultation document[1]. This Re-evaluation Decision document[2] describes this stage of PMRA's regulatory process for the re-evaluation of hexahydrotriazine as well as summarizes the Agency's decision and the reasons for it. No comments were received during the consultation process. This decision is consistent with the proposed re-evaluation decision stated in PRVD2010-06. To comply with this decision, registrants of products containing hexahydrotriazine will be informed of the specific requirements affecting their product registrations

What Does Health Canada Consider When Making a Re-evaluation Decision?

The PMRA's pesticide re-evaluation program considers potential risks, as well as value, of pesticide products to ensure they meet modern standards established to protect human health and the environment. Regulatory Directive DIR2001-03, *PMRA Re-evaluation Program*, presents the details of the re-evaluation activities and program structure.

Hexahydrotriazine, one of the active ingredients in the current re-evaluation cycle, has been re-evaluated under Re-evaluation Program 1. This program relies as much as possible on foreign reviews, typically United States Environmental Protection Agency (USEPA) Reregistration Eligibility Decision (RED) documents. For products to be re-evaluated under Program 1, the foreign review must meet the following conditions:

- it covers the main science areas, such as human health and the environment, that are necessary for Canadian regulatory decisions;
- it addresses the active ingredient and the main formulation types registered in Canada; and
- it is relevant to registered Canadian uses.

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1 "Consultation statement" as required by subsection 28(2) of the *Pest Control Products Act*.

2 "Decision statement" as required by subsection 28(5) of the *Pest Control Products Act*.

Based on the outcome of foreign reviews and a review of the chemistry of Canadian products, the PMRA has made a regulatory decision and requires appropriate risk-reduction measures for Canadian uses of hexahydrotriazine. In this decision, the PMRA took into account the Canadian use pattern and issues (e.g. the federal Toxic Substances Management Policy [TSMP]).

The USEPA re-evaluated hexahydrotriazine and published its conclusions in a 2008 RED.

For more details on the information presented in this Re-evaluation Decision, please refer to the Science Evaluation in the related Proposed Re-evaluation Decision PRVD2010-06, *Hexahydrotriazine*.

The PMRA is aware that the USEPA assessment of formaldehyde releasing active ingredients is ongoing and may re-assess hexahydrotriazine, as required.

What Is Hexahydrotriazine?

Hexahydrotriazine is an antimicrobial agent which acts by releasing formaldehyde.

Hexahydrotriazine is used as a material preservative and machine cleaner to control microbial activity in metalworking fluids and on machine surfaces. Hexahydrotriazine is also used as an in-can material preservative in water-based products such as paints, adhesives, resin solutions, printing inks, stuccos, joint compounds, cleaners, liquid detergents, fabric softeners, floor finishes and liquid polishes.

Health Considerations

Can Approved Uses of Hexahydrotriazine Affect Human Health?

Hexahydrotriazine is unlikely to affect your health when used according to the revised label directions.

People could be exposed to hexahydrotriazine by treating or handling products containing hexahydrotriazine; as well as consumption of food that may have come in contact with surfaces containing residues of hexahydrotriazine, or by entering sites where products containing hexahydrotriazine have been used. The PMRA considers two key factors when assessing health risks: the levels at which no health effects occur and the levels to which people may be exposed. The dose levels used to assess risks are established to protect the most sensitive human population (for example, children and nursing mothers). Only uses for which exposure is well below levels that cause no effects in animal testing are considered acceptable for continued registration.

The USEPA concluded that hexahydrotriazine was unlikely to affect human health provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Environmental Considerations

What Happens When Hexahydrotriazine Is Introduced Into the Environment?

Hexahydrotriazine is unlikely to affect non-target organisms when used according to the revised label directions.

Hexahydrotriazine is primarily used indoors; therefore, the potential for environmental exposure is low. The USEPA concluded that reregistration of hexahydrotriazine was acceptable provided that risk-reduction measures were implemented. These conclusions apply to the Canadian situation, and equivalent risk-reduction measures are required.

Measures to Minimize Risk

Labels of registered pesticide products include specific instructions for use. Directions include risk-reduction measures to protect human and environmental health. These directions must be followed by law. As a result of the re-evaluation of hexahydrotriazine, the PMRA is requiring further risk-reduction measures for product labels.

Human Health

- Phase out use in paint.
- Phase out manual application of machine cleaner.
- Phase out use in cleaners, liquid detergents, fabric softeners.
- Reduce application rate in metalworking fluids, hydraulic fluids, chain lubricants, and spin finish emulsions.
- Additional personal protective equipment for handlers.

Environment

Additional advisory label statements pertaining to disposing of wastewater.

Appendix I lists all required label amendments.

What Additional Scientific Information Is Required?

Data are required as a condition of continued registration under Section 12 of the *Pest Control Products Act*. The registrants of this active ingredient must provide these data or an acceptable scientific rationale to the PMRA within the timeline specified in the decision letter. Appendix II lists all data requirements.

Other Information

Any person may file a notice of objection[3] regarding this decision on hexahydrotriazine within 60 days from the date of publication of this Re-evaluation Decision. For more information regarding the basis for objecting (which must be based on scientific grounds), please refer to the Pesticides and Pest Management portion of Health Canada's website (Request a Reconsideration of Decision) or contact the PMRA's Pest Management Information Service.

[3] As per subsection 35(1) of the *Pest Control Products Act*.

Appendix I Label Amendments for Products Containing Hexahydrotriazine

The label amendments presented below do not include all label requirements for individual end-use products, such as first aid statements, disposal statements, precautionary statements and supplementary protective equipment. Additional information on labels of currently registered products should not be removed unless it contradicts the above label statements.

The labels of end-use products in Canada must be amended as follows to further protect workers and the environment.

I) The following uses are not eligible for continued registration and must be removed from end-use product labels:

- Machine cleaner when applied manually to machine surfaces not reached by circulating coolant/cleaner.
- Paints and related products.
- Cleaning products, liquid detergents, fabric softeners.

Labels of end use products intended for material preservation must be reworded such that hexahydrotriazine may only be used as a material preservative in the following uses: adhesives, resin solutions, printing ink, stuccos, joint compounds, floor finishes, and liquid polishes applied by liquid pour or metering pump up to a maximum rate of 0.24% active ingredient by weight.

II) The end-use product labels must be amended to indicate a maximum application rate:

> Application rate in metalworking fluids, hydraulic fluids, chain lubricants and spin finish emulsions must be reduced to 0.05% active by weight.

III) The following statement must be included on the primary display panel.

> CAUTION – EYE IRRITANT

The following statements must be included on the secondary display panel

> Harmful or Fatal if swallowed.
> May irritate eyes.

IV) The following statements must be included in a section entitled **PRECAUTIONS**.

> All mixers and other handlers must wear: long-sleeved shirt and long pants, shoes plus socks, chemical-resistant gloves, goggles or face shield.

Formaldehyde can be released during use of this product. Ensure that formaldehyde air concentrations in the workplace do not exceed the exposure levels established by the occupational health and safety authorities in your jurisdiction (e.g., engineering controls, monitoring). If values exceed this level, wear NIOSH-approved respiratory protection.

V) The following statements must be included in a section entitled **DIRECTIONS FOR USE**.

Machine cleaner must be added by closed transfer system.

DO NOT contaminate irrigation or drinking water supplies or aquatic habitats by cleaning of equipment or disposal of wastes.

Appendix II Additional Data Requirements

The following data are required as a condition of continued registration under Section 12 of the PCPA. The registrants of hexahydrotriazine are required to provide these data or an acceptable scientific rationale within 24 months from the date of the decision letter that will be sent by the PMRA.

DACO 10.2.3.2:
Laboratory Trials (ASTM method E2275-03: Evaluating Water-Miscible Metalworking Fluid Bioresistance and Antimicrobial Pesticide Performance.

This study must be conducted with a relevant end-use product.